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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,837	07/23/2001	Klaas Poelstra	P 280101	6405

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FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/806,837		POELSTRA ET AL.	
	Examiner		Art Unit	
	Janet L. Andres		1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7, 14 and 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-7, 14, 16-26 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 3, 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 24 October 2003 is acknowledged. Claims 1-3, 5-7, 14, and 16-30 are pending and under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Information Disclosure Statement

2. Applicant's Information Disclosure Statement filed 12 May 2003 has been considered in full and the form 1449 filed 24 October 2003 is attached. The references cited in the Search Report have also been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

Election/Restrictions

3. Applicant argues with respect to the traversal of the restriction requirement that a *de facto* traverse was presented. Applicant further argues that search of all claims would not present an undue burden because all claims were searched in the PCT search report and further found to be novel and unobvious and to have utility.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the office action of 24 July 2003, no errors in the restriction requirement were indicated. Thus the election was properly treated as an election without traverse. See MPEP §818.03 (a), cited previously:

As shown by the first sentence of 37 CFR 1.143, the traverse to a requirement must be complete as required by 37 CFR 1.111(b) which reads in part: "In order to be entitled to

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reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action. . . . The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. . . .” Under this rule, the applicant is required to specifically point out the reasons on which he or she bases his or her conclusions that a requirement to restrict is in error. A mere broad allegation that the requirement is in error does not comply with the requirement of 37 CFR § 1.111. Thus the required provisional election (see MPEP § 818.03(b)) becomes an election without traverse.

Applicant's arguments in the current response are not timely, since the restriction requirement was made final in the previous office action. However, it is noted that the opinions provided in international applications are not binding: see 37 C.F.R. 1.484. Further, while the search and examination performed for the international application are considered, further searches and additional considerations may be required. It is additionally noted that the elements of the claims that encompass the non-elected sequences have been cancelled and the traversal is thus no longer relevant.

The requirement for an election of species is withdrawn because, while no generic claim has been found to be allowable, no prior art pertaining to the use of this peptide to target cells has been found.

Claim Rejections/Objections Withdrawn

4. The objection to the specification is withdrawn in response to Applicant's amendment.
5. The objection to claims 1-7, 14, and 16-26 is withdrawn in response to Applicant's amendment.
6. The rejection of claims 25 and 26 under 35 U.S.C. 101 as being drawn to non-statutory subject matter is withdrawn in response to Applicant's amendment.

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7. The rejection of claim 3 under 35 U.S.C. 112, first paragraph, is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained

8. The rejection of claims 1, 2, 5-7, 14, and 16-26 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is maintained for reasons of record in the office action of 24 July 2003 and newly applied to new claims 28-30.

Applicant argues that the peptide can be used for targeting cells involved in sclerotic and fibrotic disease in which the PDGF receptor is upregulated, citing p. 3. Applicant argues that all cells encompassed are enabled and that other carriers can be used. Applicant argues that there is a clear difference in distribution in normal vs. diseased liver and that the invention only binds to activated stellate cells, pointing to figures 1, 3, and newly submitted figures 7-10. Applicant further cites Bejaars as evidence that the claimed invention binds to hepatic stellate cells, to fibrotic kidney cells, and to undifferentiated fibroblasts. Applicant argues that viral carrier particles can also be used.

Applicant's arguments have been fully considered but have not been found to be persuasive. Applicant's argument that other carriers can be used is found to be persuasive and this basis of the rejection is withdrawn. It is further agreed that the invention binds to activated stellate cells and to fibrotic kidney cells, as well as to fibroblasts, as is indicated on pp. 173 and 174 of Bejaars. However, these observations are not sufficient to enable the invention as broadly claimed. Claims 1, 2, 5, 6, 14, 16-24, and 28 are drawn to compositions and methods for targeting any fibrotic or sclerotic disease in which PDGF receptors are upregulated; claims 7, 25, 26, and 29-30 encompass diseases other than liver or kidney fibrosis. That the receptor is present

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in cultured fibroblasts does not render it predictable that its levels would be increased in all fibrotic diseases or increased to sufficient levels to enable it to be used as a target, nor does it indicate that it could be used diagnostically. Applicant's assertion on p. 3 that the receptors are upregulated in fibroblasts in "various organs" (line 2) does not provide guidance to allow one of skill in the art to predictably make and use the invention as broadly claimed. As stated in the office action of 24 July 2003, there is no evidence to indicate that other damaged tissues could be targeted. There are no teachings as to what levels are present in what types of damaged tissue, nor is any objective evidence presented to indicate that the peptide would target "sclerotic or fibrotic" tissue as broadly claimed. Applicant has provided no guidance beyond the presentation of evidence that the invention can bind to fibroblasts in cell culture. Cells in culture can have very different characteristics from cells in tissue, due to such factors as the adaptation of cells to survival in culture, the effects of three-dimensional structure and of surrounding cells, and the complex physiological factors that influence cells *in vivo*. Thus the ability of the peptide to bind to fibroblasts in culture is not sufficient guidance to indicate that it could predictably be used to target diseased tissues, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. What is provided is thus the idea for an invention, and the invitation to experiment to implement this invention, not the invention itself.

Allowable Subject Matter

9. Claims 3 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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CLAIMS 1, 2, 5-7, 14, 16-26, AND 28-30 ARE REJECTED. CLAIMS 3 AND 27 ARE OBJECTED TO.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

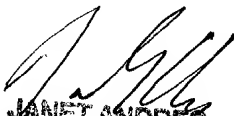
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All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

January 12, 2004


JANET ANDRES
PATENT EXAMINER